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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751

2292 7590 02/02/2007
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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/02/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/02/2007.

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Office Action Summary	Application No.	Applicant(s)	
	10/715,482	ARORA ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,21 and 35-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,3-8,21 and 35-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to Applicant's amendment and remarks filed October 30, 3006.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and remarks the rejection under 35 U.S.C. 112 second paragraph, page 16, paragraph 9 is withdrawn.

Rejection Maintained

4. The rejection of claims 1, 3-8 and 21 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 2-4, paragraph 3 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph as containing subject matter which lacks written description in the specification in such a way as to enable one skilled in the art to which it pertains or with which it is most nearly connected to make and/or use the invention.

The claims are directed to a novel protein capable of inhibiting anthrax toxin activity. Dependent claims 2 and 21 recite "... wherein the protein is isolated from pollen grains of a grass of a genus selected from the group consisting of *Imperata,* a genus related to *Imperata*, *Lolium*, a genus related to *Lolium*, *Phleum*, a genus related to *Phleum*, *Cynodon* and a genus related to *Cynodon*" and "...wherein the grass is selected from the group consisting of *Imperata cylindrica, Lolium perenne, Phleum pretense* and *Cynodon datylon*". Therefore, the claims encompass a genus of 67 kDa proteins.

The specification only provides written description for the 67 kDa protein isolated from *Imperata cylindrica*. There is no disclosure that the claimed protein was isolated from a grass other than *Imperata cylindrica.* The instant specification does not describe a 67 kDa protein isolated from pollen grains of a grass of a genus selected from the group consisting of *Imperata,* a genus related to *Imperata*, *Lolium*, a genus related to *Lolcium*, *Phleum*, a genus related to *Phleum*, *Cynodon* and a genus related to *Cynodon*". The specification also fails to provide adequate written description for claimed protein isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon.*

Bijli et al (*Clin. Exp. Allergy, January 2003, 33:65-71)* teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Therefore, one of skill in the art would not conclude that the claimed novel 67-kda protein could be isolated from a grass other than *Imperata cylindrica*. One skilled in the art would not conclude that Applicant was not in possession of the claimed 67 kDa proteins isolated from the genus of *Lolium, Cynodon* and *Phleum* at the time of filing. Therefore, Applicant has not met the written description requirements as set forth in 35 U.S.C. 112, first paragraph.

Applicant's Arguments

Applicant urges that Applicants have named a number of species of grasses from which the protein of the instant invention may be obtained. Applicant urges that Figure 3 shows an immunoblot and ELISA tests of extracts from the named plants using serum from allergic patients showing the presence of a 67 Kda IgE binding protein. Applicant urges that the Examiner mistakenly requires that that Applicant limit their claims to the subject matter that has actually been reduced to practice.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 25, 2006 have been fully considered but they are not persuasive.

It must be remembered that this rejection is made under 35 U.S.C. 112, first paragraph and is set forth as a written description rejection. It must be also be remembered that 35 U.S.C. 112, first paragraph (written description) requires that

Applicants were in possession of the claimed invention at the time of filing. The rejection under 112 first paragraph was set forth because according to the instant disclosure, Applicants were only in possession of a 67 kDa protein that was isolated from *Imperata cylindrical* and not from that other genus such as *Lolium*, *Phleum* and Cynodon. It is established in art that the claimed 67 Kda protein can be isolated from *Imperata cylindrical.* Nowhere in the instant specification have Applicants disclosed a 67 kDA protein isolated from other genus such as *Lolium*, *Phleum* and *Cynodon* as claimed by Applicants. Therefore, the specification also fails to provide adequate written description for claimed protein isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon.* Therefore, one skilled in the art would not conclude that Applicants were in possession of 67 kDa proteins isolated from *Lolium perenne, Phleum pretense* or *Cynodon datylon* at the time of filing.

To address Applicant's comments regarding cross-reactivity and Figure 3(a) of the instant specification, figure 3(a) shows cross-reactivity of 67 kDa hypersensitive sera to *Imperata cylindrica, Cynodon dactylon, Lolium perenne and Phleum prastense.* This figure does not show evidence that Applicant's were in possession of the claimed invention at the time of filing of a 67-kDa protein isolated from the genus related to *Imperata*, *Lolium,* a genus related to *Lolium*, *Phleum*, a genus related to *Phleum, Cynodon* and a genus related to *Cynodon.* The figure shows cross-reactivity of 67 kDa hypersensive sera specific to *Imperata cylindrica, Cynodon dactylon, Lolium perenne and Phleum prastense.* See page 6 of the instant specification. Figure 3 in no way shows that tropical grasses; *Cynodon dactylon, Lolium perenne and Phleum*

prastense have a 67-kDA protein. At most the specification shows that *Cynodon dactylon, Lolium perenne and Phleum prastense* have at least one common epitope.

For the reasons set forth above, this rejection is maintained.

5. The rejection of claims 1, 3-8 and 21 under 35 U.S.C. 112, first paragraph is maintained for the reasons set forth on pages 5-9, paragraph 4 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed to a novel protein capable of inhibiting anthrax toxin activity.

The specification teaches that the protein of the invention can inhibit activity of anthrax toxin (page 2). The specification teaches that the protein has the utility for developing a therapeutic agent that can reduce the toxic effects once the disease has set in (page 2). Therefore the instant specification contemplates the use of the claimed 67 kDa protein to treat anthrax *in vivo*. The claims recites the claim limitation "dose dependent manner" (e.g. claim 1) as well as reciting the specific concentrations of the claimed protein (e.g. claims 5-8). Claim 13 recites the limitation "wherein said protein inhibits anthrax toxin *in vitro*". Thus, the instant specification contemplates *vitro* use. The specification only discloses inhibition studies *in vitro* using claimed 67 kDa protein incubated with J774A.1 (eukaryotic) cells (pages 7-8). The specification has failed to correlate *in vivo* treatment of anthrax using the claimed protein and the *in vitro* treatment of anthrax using the claimed protein. The specification teaches that the novel protein for inhibition of activity of anthrax and the purified protein has the ability or reduce the toxic effects of anthrax (page 2). What toxic effects are reduce? The toxic effects of PA or LF or both or other toxins? What constitutes a reduction? The specification and claims teach that the claimed 67-kDa protein has IgE binding properties. The specification further teaches *in vitro* assays using the claimed protein and *Imperata cylindrica* (Ic) hypersensitive individual's sera, 10 out of 12 sera demonstrated it to be a major allergen (page 6 and Figure 2). Example 7 of the instant specification teaches that the 67 kDa protein was "preincubated" with the J774A.1 cell line in an *in vitro* assay. Therefore, a "preincubation" of the protein with the cells is required. How does this correlate with administering the 67 kDa protein *in vivo*? Will the protein effective *in vivo* if preincubation is not possible? How is the preincubation requirement met *in vivo*? Does

the 67 kDa protein reach the reach the target site to inhibit the PA and LF antigens? Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* teach that grass pollen allergens have been implicated in the induction of type I allergic disorders in atopic individuals (page 251). Verma et al teach that the 67 kDa protein isolated from *Imperata cylindrica* Pollen Extract showed high IgE binding in ELISA and reacted with 80% of the patients' sera and suggest that the 67 kDa protein may be a new allergen (page 255). Vieths et al (*Ann N.Y. Acad. Sci., 964:47-68, 2002)* teach that pollen-allergic patients frequently present allergic symptoms after ingestion of several kinds of plant-derived food (see the Abstract). Vieths et al teach that approximately 15-20% of the population in developed countries are allergic to pollen and 50-93% of birch pollen-allergic patients have IgE mediated reactions to pollen related foods (page 48). Vieths et al teach that at the molecular level, observations are based on the cross-reactions of human IgE antibodies which are directed against pollen allergens with homologous allergens in plant food (page 48). How would the claimed 67 kDa protein react when administered *in vivo* to patients that produce high levels of IgE neutralizing antibodies due to allergic reactions? Zhao et al *(Human Antibodies, 2003; 12(4):129-35)* teach that neutralizing monoclonal antibodies can block the action of anthrax toxin lethal toxin factor formation (see the Abstract). If neutralizing antibodies are to LF are present, how is the claimed protein when administered *in vivo*? The experimental examples of the instant specification are directed to *in vitro* use. However, the instant specification contemplates both *in vivo* and *in vitro* use of the claimed protein. The instant specification has not presented disclosure that would lead one of skill in the art to conclude that the *in vitro* data present in the specification would correlate with *in vivo* use.

One of skill in the art could have reason to doubt the assertion that the claimed 67 kDa protein would be effective in inhibiting anthrax *in vivo* based on the teachings of the cited art and the absence of evidence in the instant disclosure to correlate inhibition of the anthrax toxins with in vivo administration of the claimed protein.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to using the claimed protein to inhibit the anthrax toxin *in vivo* 3) there are no working examples which suggest the desired results of a successful use of the claimed protein and 4) the relative skill of those in the art is commonly recognized as quite high (post - doctoral level).

In view of all of the above, it is determined that the specification has not provided guidance that would enable one of skill in the art to be able to use the claimed invention commensurate with the claims. One of skill in the art would require undue

experimentation to determine whether the claimed 67 kDa protein can be used to treat or inhibit anthrax toxins *in vivo*.

Applicant's Arguments

Applicant urges that their burden in writing the specification is merely to establish by a preponderance of the evidence not beyond reasonable doubt or even clear and convincing evidence that the protein in question would have the utility asserted and so that the use of the invention is enabled. Applicant urges that the specification has demonstrated that the protein of the invention is able to inhibit anthrax toxin *in vitro*. Applicant refers to Example 7 of the instant specification. Applicant urges that the tissue experiment is similar to in vitro treatment and can be extrapolated thereto. Applicant urges that the experiment clearly indicates that the 67 kDa protein blocks the entry of anthrax toxin and that a higher number of cells survived toxin exposure due to this treatment. Applicant urges that a protective antigen is the name of the anthrax protein which on cleavage allows lethal factor or edema factor to bind and thereby these proteins enter the cells to give bio-chemical activity. Applicant urges that the 67-kDa protein inhibits the activity of anthrax toxin protective antigen thereby the enzymatic proteins (LF or EF) are not delivered to the cytosol of cells.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 25, 2006 have been fully considered but they are not persuasive.

This rejection is set forth because the instant disclosure teaches that the protein of the invention can inhibit activity of anthrax toxin. The instant specification has failed to correlate *in vivo* treatment of anthrax using the claimed protein and the *in vitro* treatment using the claimed protein. Previously cited references have taught that the 67- kDa protein isolated from *Imperata cylindrical* show high IgE binding and at the molecular level, observations are based on the cross-reactions of human IgE antibodies which are directed against pollen allergens with homologous allergens in plant food. Therefore, how would the claimed 67 kDA protein react when administered *in vivo* to patients that produce high levels of IgE neutralizing antibodies due to allergic reactions? It should be remembered that the instant specification contemplates the use of the claimed 67 kDa protein to treat anthrax *in vivo* and within this scope patients with high levels are included. One of skilled in the art would not conclude that the claimed 67 kDa protein would be effective in inhibiting anthrax *in vivo* based on the teachings of the cited art and the absence of evidence in the instant disclosure to correlate inhibition of the anthrax toxins with *in vivo* administration of the claimed protein.

To address Applicant's comment regarding Example 7 of the instant specification, Example 7 of the instant specification teaches that the 67 kDa protein was "preincubated" with the J774A.1 cell line in an *in vitro* assay. Therefore, a "preincubation" of the protein with the cells is required. How does this correlate with administering the 67 kDa protein *in vivo*? Will the protein be effective *in vivo* if preincubation is not possible? How is the preincubation requirement met *in vivo*? Does the 67 kDa protein reach the target site to inhibit the PA and LF antigens?

Applicant has failed to show how the claimed protein can be used to treat anthrax *in vivo* which is contemplated by the instant disclosure.

To address Applicant comment regarding the 67-kDa protein isolated from *Imperata cylindrical* as being a protective antigen. It should be noted that protective immunity is different from using the claimed protein as a therapeutic agent. Applicant has not disclosed in the instant specification examples in which the claimed protein is administered to a subject (*in vivo*) and challenge studies are performed. Thus, the skilled artisan would not conclude that the claimed protein can be used to provide "protective immunity" or be of any therapeutic value against anthrax.

Applicant has failed to teach how to make and use the claimed invention as required under 35 U.S.C. 112, first paragraph. Therefore, the rejection is maintained.

6. The rejection of claims 1, 3-8 and 21 under 35 U.S.C. 102(a) as anticipated by Bijli et al *(Clin. Exp. Allergy, January 2003)* is maintained for the reasons set forth on pages 9-11 paragraph 5 of the previous Office Action.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Bijli et al teach a protein that is stable at room temperature (see Abstract). Bijli et al teach a 67kDa protein binds IgE (page 68). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner", "is devoid of any carbohydrate moiety", "wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to

show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Bijli et al do not teach an isolated 67-kDa protein. Applicant urges that the protein of the prior art was only observed on SDS-PAGE. Applicant urges that Bijli et al do not teach an isolated or purified protein.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 25, 2006 have been fully considered but they are not persuasive.

Bijli et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2).

To address Applicant's comments regarding purification, it should be noted the claims are directed to a product and Applicant is arguing process limitations (e.g. the protein of the prior art was only observed on SDS-PAGE which are not in the claims. It should be further noted that the claims do not recite how the protein is isolated. It should be remembered that isolate is defined as separating something from something else. Thus, the prior art teaches that the 67-kDa protein has been isolated on SDS gel. See page 68. Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior

art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2003 anticipate the claimed invention.

7. The rejection of claims 1-8 and 21 under 35 U.S.C. 102(b) as anticipated by Bijli et al *(Journal of Immunological Methods 260 (Feb. 2002, 91-96)* is maintained for the reasons set forth on pages 11-12, paragraph 6 of the previous Office Action.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" "wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Bijli et al, 2002 fails to teach that a 67-kDa protein is isolated from *Imperata*. Applicant urges that Bijli 2002 urges that proteins or degraded proteins of high molecular weight separates around the same molecular weight. Applicant urges that Bijli et al did not separate the claimed 67 kDa protein.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 25, 2006 have been fully considered but they are not persuasive.

Bijli et al do teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, pages 92-93 and Figure 1). Bijil et al teach that the samples were prepared by the method of Kumar et al, 1998 which teaches a pollen extraction method. Therefore, the proteins were extracted from *Imperata cylindrica*. Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2002 anticipate the claimed invention.

8. The rejection of claims 1-8 and 21 under 35 U.S.C. 102(b) as anticipated by Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* is maintained for the reasons set forth on pages 13-15, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Verma et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Verma et al teach a protein that is stable at room temperature (page 252). Verma et al teach the 67-kDa protein is a cross-reactive allergen (see the Abstract). Verma et al teach that the 67-kDa protein has at least three antigenic determinants (see the Abstract). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20

ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that the isolated protein of Verma et al is different from the claimed isolated protein. Applicant refers to the declaration submitted under 37 CFR. 1.1.32 filed February 6, 2006. Applicant states that Verma et al's protein is different from the presently claimed protein because the claimed protein can be sequenced using Edman degradation where as Verma et al 's protein cannot be sequenced and Verma et al purify their protein to a single band by SDA-PAGE analysis using ion exchange chromatography and find that the amino terminus is blocked and consequently no sequence can be obtained. Applicant refers to figure 1. Applicant urges that Verma cannot anticipate the claimed invention.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed October 25, 2006 have been fully considered but they are not persuasive.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1-8 and 21 based upon Verma et al as

set forth in the last Office action. Verma et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, page 252 and Figure 4). Verma et al also teach that the 67 kDa protein was purified using various chromatography methods (page 252). To address Applicant's comment regarding the protein bands disclosed on the immunoblots of the prior, it should be noted that among the protein bands disclosed, the prior art teaches a stable 67 kDa protein. See pages 253 and 254, figure 2, Ic-VIII.

The claims are directed to an isolated 67-kDa protein and not a purification method for obtaining the isolated 67 kDa protein. The product (e.g. 67-kDa protein) of Verma et al is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to

which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Applicant's arguments regarding the inability of Verma et al's protein to be sequenced, it should be noted that there are no limitations in the claims that require that the protein is sequenced. Applicant has not shown any structural differences between the claimed 67-kDa protein and the 67Kda protein taught by Verma et al. Applicant has provided no side-by-side comparison to show that the claimed protein differs from that of the prior art reference. Since the protein of the prior art and the claimed protein are the same the protein of the prior art would necessarily possess all of the same biological activities as the claimed protein. Verma et al anticipate the claimed invention.

9. The rejection of claims 1, 3-8 and 21 under 35 U.S.C. 112, second paragraph is maintained for the reasons set forth on page 16, paragraph 8 of the previous Office Action.

The rejection was on the grounds that Claims 1, 3-8 and 21 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 in particular recites "...a 67-kDa protein isolated from "the genus related to *Imperata*", "genus related to *Lolium*" , "a genus related to *Phleum*" and "*a* genus related to *Cynodon*." It is unclear as to what Applicant is referring. Clarification is required.

Applicant's Arguments

Applicant urges that the claim language is not indefinite. Applicant urges that those skilled in the art would understand the metes and bounds of such language.

Examiner's Response to Applicant's Arguments

It is the Examiner's position that the language is indefinite. For example, *Imperata* is the name of genus. Therefore, the phrase "the genus related to *Imperata*" is unclear.

10. Claims 1, 3-8 and 21 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 6 in particular recites "...partially inhibits..". It is unclear as to what Applicant is referring. Clarification is required.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

12. No claims are allowed.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571.272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vanessa L. Ford
Biotechnology Patent Examiner
January 16, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER